Health Facilities and Services Eligible for Certificate of Need Review SUMMARY

(**bold** currently reviewed in Washington, *italics* referenced in ESSHB 1688)

Proposed to Not Review

Acute Inpatient

Substance abuse (adult)

Substance abuse (child/adolescent)

Intensive care unit (ICU)/Critical care unit

Adult ICU

Long Term Care

Boarding homes (assisted living facility)

Specialty care assisted living facility

Intermediate care mentally retarded facility

Swing beds (>5 beds)

Residential care facility

Psychiatric residential treatment facility

Adult family homes

Medical Equipment

Hyperbaric chambers

Ultrasound

Heart-lung bypass machines

Outpatient Services

Behavioral health services

Opiate replacement treatment facilities (methadone)

Urgent care facilities

Substance Abuse Services

Community clinic

Procedures

Primary/emergent angioplasty

Lithotripsy

Surgery

General Inpatient
Outpatient (hospital)

Other Services

Information technology
Medical office buildings

Birthing Centers

Proposed to Continue Review

Acute Inpatient

Medical-Surgical Licensed Beds

Rehabilitation (Level I)

Psychiatric (licensed)

Obstetrics (Level II & III)

Pediatrics (specialty) includes ICU

Neonatal ICU (Level II & III)

Burn Units (specialty)

Specialty hospitals (heart, orthopedic, surgical)

Long Term Care

Subacute care (Medicare distinct part)

Long term care hospital

Nursing homes

Contg. care ret. center (5-yr Medicaid life care req)

Medical Equipment

(none)

Outpatient Services

(none)

Procedures

Therapeutic cardiac catheterization

Elective angioplasty

Kidney treatment centers (including hemodialysis)

Surgery

Outpatient-any freestanding ambulatory center (ASC)

Open heart (adult)
Open heart (pediatric)

Solid organ transplant (adult)

Solid organ transplant (pediatric)
Bone marrow/stem cell transplants

Single-specialty Freestanding ASCs open to non-

owner practitioners

Other Services

Home health care (Medicare/Medicaid eligible)

Hospice care centers (inpatient)

Hospice agencies (outpatient, Medicare/Medicaid)

(see the following pages for details)

Proposed for Future Study or Potential Regulation as New Consideration

Acute Inpatient

Pediatric ICU (none)

Long Term Care

(none)

Medical Equipment

Cyber knives

Computed tomography (CT) scanners

Gamma knives

Magnetic resonance image scanners

Positron Emission Tomography (PET) scanners

PET/CT scanners Linear accelerators Robotic Surgery

Outpatient Services

Freestanding emergency departments

Freestanding radiological service centers

Diagnostic imaging centers

Oncology (Cancer) Treatment Centers

Procedures

Diagnostic cardiac catheterization

Surgery

Cardiac

Physician practice office-based surgery
All ASCs regardless of owner or operator

Other Services

Emerging technology and new service categories

Research and demonstration projects

Air ambulance

Home health care

Hospice agencies

No financial review thresholds

All CON-reviewed items should be licensed Data systems should be linked to licensure

Consider MO regulation related to research studies

Worksheet of Health Services and Situations Eligible for Certificate of Need Review (bold reviewed in Washington, italics referenced in statute)

New	Expsn ¹	NOrv ²	Type of Service	Guiding Principles ⁴
			Acute Inpatient Medical-Surgical Licensed Beds Rehabilitation (Level I) Psychiatric (licensed) Obstetrics (Level II & III) Pediatrics (specialty)) Substance abuse (adult) Substance abuse (child/adolescent) Intensive care unit (ICU)/Critical care unit Neonatal ICU (Level II & III) Adult ICU Pediatric ICU Burn Units (specialty) Specialty hospitals (heart, orthopedic, surgical)	specific needs of area, accessibility, impact of new health facilities on expenditures specific needs of area, accessibility, impact of new health facilities on expenditures acessibility, affect on facilities for uninsured/underinsured positive impact on outcomes postive impact on outcomes, affect on underinsured and uninsured data to indicate high quality health care, impact on outcomes positive impact on outcomes, underinsured/uninsured specific health needs of area substantial risk for inappropriate utilization, underinsured/uninsured, total health \$\$
			Long Term Care Subacute care (Medicare distinct part) Boarding homes (assisted living facility) Specialty care assisted living facility Intermediate care mentally retarded facility Long term care hospital Nursing homes Swing beds (>5 beds Residential care facility Psychiatric residential treatment facility Continuing care ret. center (5-yr Medicaid life care req) Adult family homes	specific health needs of the area specific health needs of area, positive impact on outcomes, state funds to cover \$\$ specific needs of area, positive impact on outcomes, state funds to cover \$\$ specific needs of area specific needs of area
			Medical Equipment Cyber knives Computed tomography (CT) scanners Gamma knives Hyperbaric chambers Magnetic resonance image scanners Positron Emission Tomography (PET) scanners PET/CT scanners Linear accelerators Robotic Surgery Ultrasound Heart-lung bypass machines	total health expenditures, specific health needs of area, impact on quality outcomes substantial risk for inappropriate utilization, accessibility total health expenditures, specific needs of area, impact on quality outcomes substantial risk for inappropriate utilization substantial risk for inappropriate utilization substantial risk for inappropriate utilization (cumlative radiation,etc) specific needs of area, state funds to cover increased \$\$ specific needs of area, state funds to cover increased \$\$

Worksheet of Health Services and Situations Eligible for Certificate of Need Review (bold reviewed in Washington, italics referenced in statute)

New	Expsn ¹	NOrv ²	Type of Service	Guiding Principles ⁴
			Outpatient Services Freestanding emergency departments Freestanding radiological service centers Behavioral health services Opiate replacement treatment facilities (methadone) Urgent care facilities Diagnostic imaging centers Oncology (Cancer) Treatment Centers Substance Abuse Services Community clinic	affect on underinsured/uninsured, accessibility substantial risk for inappropriate utilization, specific needs of area substantial risk for inappropriate utilization, specific needs of area substantial risk for inappropriate utilization, specific needs of area
			Procedures Diagnostic cardiac catheterization Therapeutic cardiac catheterization Elective angioplasty Primary/emergent angioplasty Lithotripsy Kidney treatment centers (including hemodialysis)	positive impact on quality outcomes, substantial risk for inappropriate utilization positive impact on quality outcomes, substantial risk for inappropriate utilization positive impact on quality outcomes, substantial risk for inappropriate utilization substantial risk for inappropriate utilization, postive impact on quality outcomes
			Surgery Cardiac General Inpatient Outpatient (any freestanding ambulatory) Outpatient (hospital) Open heart (adult) Open heart (pediatric) Solid organ transplant (adult) Solid organ transplant (pediatric) Bone marrow/stem cell transplants Single-specialty freestanding ambul. surgery centers Physician practice office-based surgery Hospital-based ambulatory surgery center	substantial risk for inappropriate utilization, postive impact on qualtiy outcomes substantial risk for inappropriate utilization, underinsured/uninsured accessibility, positive impact on outcomes, data/QI., total health expenditures accessibility, positive impact on outcomes, data/QI., total health expenditures accessibility, positive impact on outcomes, data/QI., total health expenditures accessibility, total health expenditures, data/QI accessibility, total health expenditures, data/QI substantial risk for inappropriate utilization, underinsured/uninsured, total \$\$ substantial risk for inappropriate utilization, impact on quality and outcomes substantial risk for inappropriate utilization, postive impact on quality outcomes
			Other Services Home health care (Medicare/Medicaid eligible) Hospice care centers (inpatient) Hospice agencies (outpatient, Medicare/Medicaid) Air ambulance Information technology Medical office buildings Emerging technology and new service categories Birthing Centers Research and demonstration projects	data for QI, substantial risk for inappropriate utilization, specific needs of area specific needs of area specific needs of area state funds to cover increased \$\$ total health expenditures, state funds to cover increased \$\$, risk for inappropriate use impact of new health services on quality and

¹Expansion ²NO Review of Service ³More information must be considered as qualifiers to some services

Health Facilities and Services Eligible for Certificate of Need Review

(background information provided by TAC members to comment on selections)

General Qualifiers and Considerations:³

- 1. We need to list the potential or actual state "levers" that exist or need to be strengthened to get the outcomes we want/desire. CON is only one of those levers. The others are Licensure, Accreditation, EMS certification (of Emergency Departments and their levels), and others.
- 2. We need to recommend how to accomplish the goals of access, cost and quality. For example, the licensure for Emergency Departments should require that they be attached to a "full service" hospital; then there would be no need for a CON for "freestanding Emergency Departments". For imaging, the most important objectives are cost, access and quality. The accreditation "seal" could address the utilization and quality better than reviewing all these imaging purchases through a CON process.
- 3. The "hot potatoes" that we left unresolved are:
 - a. Imaging: of all types (including nuclear), should they be regulated; if yes, how? In a world of such rapidly changing technology, where the life span of the equipment is longer than the time to "the new, new thing", a ponderous CON process seems inappropriate. The unstated issues for imaging include rapid increases in utilization, hospital vs. free standing, radiology vs. other specialties, ownership; equipment capabilities vs. actual performance of the test (quality of interpretation), and patient safety (especially radiation exposure). Rather than deal with the politics, accreditation is a better idea than the CON process.
 - b. Ambulatory surgery of all types including hospital based, freestanding multi-specialty, freestanding single-specialty, and "in office" surgery suites. The "fair treatment" principle may apply: if you do it to one entity, you should do it to the other (what ever "it" may be)
 - c. Radiation therapy including linear accelerators, cyber knives, gamma knives, proton beam, brachytherapy and others. Licensure and Accreditation seem more relevant.
 - d. Emerging technologies and research.
- 4. The two most important criteria for "what's included in CON" are:
 - a. Maintaining the fragile state-wide publicly-funded hospital infrastructure (so something that would remove 20% of revenues and impact the functioning of a hospital would be a concern, while some service that impacted less than 3% of revenues [as an example] would not be a concern, just the changes in health care over time).
 - b. Regionalizing a very limited number of services that are low-volume, high-risk, high-cost and require complex multi-specialty interactions (solid organ transplantation and pediatric complex cases are examples).
- 5. Because of the potential impact on total expenditures as well as the potential impact on quality outcomes (including issues like exposure risk), major pieces of medical equipment needed to be considered for inclusion in the scope of coverage of a CON program.
- 6. There are concerns that new facilities be reviewed to determine whether they will be serving Medicaid consumers (and perhaps Medicare), what their charity care policies are, and the kinds, quality and amount of other health-related community benefit activities they might provide. For long term care facilities like nursing homes and ICF-MR facilities, there should be some consideration of the availability of community-based alternatives, such as through the Medicaid Home and Community Based Waiver programs before approval is granted.
- 7. There is no column to reflect "community benefits" or "community health outcomes review," which is different from licensure or accreditation and properly part of CON. Certificate of Need currently considers charity care provision (at least related to hospitals see RCW 70.38.115), and if CON is going to be linked to community health outcomes and statewide planning, then all new facilities should at least submit information about how they will impact community health outcomes through at least the above considerations. This kind of review should also be included in the full-blown CON review.
- 8. We must be sure we would take into account the impact on home health and home care agencies that are not state-contracted, but who provide in-home services. HCBW programs are separate from In-Home services programs, but do have some overlap. Regarding new ICF of SNFs, both the waiver programs and other in-home services programs would impact the need for new facilities.

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- 9. Mention was made of licensure and certification requirements, and how they overlap or don't overlap the CON process; they mostly don't. There are things in the CON requirements that are never looked at in the licensure surveys. Except for a requirement in the Medicare Hospice regulations for the use of volunteers at a specified number of hours and the requirement that care not be denied for inability to pay, there is no other regulatory requirement in the In-Home Services arena that licensure staff would review regarding charity care. The same can be said regarding access. A Medicare-certified agency (home health or hospice) could specify they will cover Xyz County, but for whatever reason doesn't, and this will not ever become part of the licensure survey process.
- 10. Level IIa Obstetrics/Neonatal services should not be reviewed. If the Perinatal Guidelines (2005 developed) were codified and a differentiation were made in the CON application and approval process to differentiate "a" from "b" in the Levels, then these could be separated in the consideration and application process. Also, because they do not currently differentiate the "a" from the "b" in Level II (or Level III for that matter), it is not "clear" what capability a particular facility has and should be held accountable to during licensure review and other processes.
 - 11. It is in the best interest of Washington State for CON to be retained for home health and hospice agencies that provide services to Medicare and Medicaid recipients because it is the key factor to assuring access to these cost effective services for this population. Home Health and Hospice community strongly advocates for preservation of existing hybrid approach to CON coverage versus licensure.

In Washington State, while all home health and hospice agencies are required to be state licensed, a certificate of need is only required for home health and hospice agencies that want to participate in the Medicare or Medicaid programs. There is no certificate of need requirement in the private pay marketplace. The reason for this "hybrid" system is similar to the rationale for hybrid automobiles. It allows for the most efficient use of our limited resources. At the present time, 70 of the 132 state licensed home health agencies are Medicare certified. For hospice agencies, all but one of the 34 state licensed agencies is Medicare certified.

The bottom line is that patients whose care is more costly to deliver because they live in rural or remote areas of the state or require more extensive, medically complex services are most likely to fall through the cracks when competition is unrestricted. When this happens, we could reasonably expect increased admissions to hospitals, and increased demand for nursing home or adult family home beds as patients are unable to remain safely in their own homes. The overall result would be chaos in this sector of health care delivery system and a significant disruption to a well thought out, historically beneficial system designed to assure access to home health and hospice services to all Medicare/Medicaid eligible patients.

- 12. More dialogue is needed on the recommendation to keep Air Ambulance groups out of the CON process. Maybe air ambulance services should be subject to CON. The concern is patient safety and expertise of the flight crew transporting the patient. Out-of-state companies may be inclined to set up contracts with hospital groups and fall short of needed expertise and equipment for the pediatric population. Also, very specific pediatric policies and protocols need to be established along with access to the pediatric medical control in a particular area.
- 13. The burden of proof should be on the applicant. Interested parties that can participate in the review process, and any appeal, should include community members and groups that will be impacted by the CON approval or denial.
- 14. The data sources used to monitor health services should include charity care data and Medicaid/Medicare contracts over time (so an entity doesn't contract with Medicaid to get CON and then drop the contract).
- 15. There should be consideration of limiting the licensing of beds that are unused, Disaster planning needs should also be a consideration, and excess capacity disclaimers should be added when determining the need for additional capacity.
- 16. Special considerations should be made in the review criteria for Critical Access Hospitals which qualify under the Federal cost-reimbursement program as a short-stay safety-net acute care inpatient hospital for rural areas.

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(background information provided by TAC members to comment on selections)

Statutory Guiding Principles:4

The Task Force is to be guided by considering the following principles:

- 1. Impact of the supply of health services on utilization.
- 2. Effect of new health services/facility on expenditures.
- 3. Impact of new health facilities/services/equipment on quality and outcomes.
- 4. Current coverage of facilities and services is to remain.

The Task Force is to develop criteria, including consideration of:

- 1. Public Need:
 - a) Specific health needs of an area
 - b) Positive impact on health indicators of population served
 - c) Substantial risk for inappropriate utilization
 - d) Accessibility for all residents
 - e) Data to indicate OI
- 2. Impact on orderly economic development of health facilities and health resources:
 - a) Impact on total health expenditures
 - b) Affect on existing providers and facilities service for underinsured/uninsured
 - c) Availability of state funds to cover increased cost
 - d) Potential of more effective or accessible or less costly alternatives

(literal quotes from ESSHB 1688)

- Sec. 3.1. In conducting the certificate of need study and preparing recommendations, the task force shall be guided by the following principles:
 - (a) The *supply of a health service can have a substantial impact on utilization* of the service, independent of the effectiveness, medical necessity, or appropriateness of the particular health service for a particular individual;
 - (b) Given that health care resources are not unlimited, the impact of any new health service or facility on overall health expenditures in the state must be considered;
 - (c) Given our increasing ability to undertake technology assessment and measure the quality and outcomes of health services, the likelihood that a requested new health facility, service, or equipment will improve health care quality and outcomes must be considered; and
 - (d) It is generally presumed that the services and facilities currently subject to certificate of need should remain subject to those requirements.
- Sec. 3.2. The task Force shall, at a minimum, examine and develop recommendations related to the following issues: . . .
 - (d) The criteria for review of certificate of need applications, as currently defined in RCW 70.38.115, with the goal of having criteria that are consistent, clear, technically sound, and reflect state law, including consideration of:
 - (i) Public need for the proposed services as demonstrated by certain factors, including, but not limited to:
 - (A) Whether, and the extent to which, the project will substantially address specific health problems as measured by health needs in the area to be served by the project;
 - (B) Whether the project will have a positive impact on the health status indicators of the population to be served;
 - (C) Whether there is a substantial risk that the project would result in inappropriate increases in service utilization or the cost of health services;
 - (D) Whether the services affected by the project will be accessible to all residents of the area proposed to be served; and
 - (E) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project, including whether there is data to indicate that the proposed health services would constitute innovations in high quality health care delivery;
 - (ii) Impact of the proposed services on the orderly and economic development of health facilities and health resources for the state as demonstrated by:
 - (A) The *impact of the project on total health care expenditures* after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
 - (B) The impact of the project on the ability of existing affected providers and facilities to continue to serve uninsured or underinsured residents of the community and meet demands for emergency care;
 - (C) The availability of state funds to cover any increase in state costs associated with utilization of the project's services; and
 - (D) The likelihood that more effective, more accessible, or less costly alternative technologies or methods of service delivery may become available;